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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,988	07/11/2003	Frank Fan	P51167C1	4244

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 03/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/617,988	FAN ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 July 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/11/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Claims 1-17 are currently pending. Claims 1-17 are considered for examination.

Priority

2. This application filed on July 11, 2003 is a CON of 09/942,487 filed on 8/30/3001, now abandoned, which claims benefit of US provisional 60/229,965 filed on 9/1/2000.

Information Disclosure Statement

3. The Information Disclosure Statement filed on July 11, 2003has been entered and considered.

Objection to the Drawings

4. The drawings are objected because of the following informalities:

(i) This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply the requirements of 37 CFR 1.821 through 1.825.

The instant application recites sequences that are not identified by SEQ ID No. (see at least Fig. 3) recite a nucleic acid sequence / amino acid sequence with more than 10 nucleotides or 4 amino acids, which is not identified by SEQ ID NO.).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international

application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

A. Claims 1-6, 8, 12-17, are rejected under 35 U.S.C. 102(a) as being anticipated by Trias et al. (WO 99/52926).

With reference to the instant claim 1, 6, Trias et al. teach a method for identifying a target of an antimicrobial compound (see page 7, lines 8-11, page 71, lines 26-31, page 72, lines 1-3, claim 36) comprising (a) cloning the open reading frame of a gene or essentially all genes of a prokaryotic organism into an expression vector comprising inducible promoter (see page 5, lines 26-30, page 6, lines 26-31, page 7, lines 1-3, page 22, line 1-31, page 71, lines 26-31, claim 36); (b) inducing expression of the gene with an inducer in the presence of an antimicrobial compound (see page 5, lines 3-30, page 72, lines 1-2, claim 36); (c) comparing growth of cells from induced gene expression in the vector to cells from uninduced gene expression in the vector (see page 5, lines 3-30, page 44, line 12-31, page 73, lines 5-6, claim 51); (d) correlating the comparison to determine if the gene is resistant to the antimicrobial compound and is target of the compound (see page 7, lines 25,29, Fig.4, page 5, 3-30, page 71, lines 26-31, page 72, lines 1-3, claim 36, page 73, lines 29-30, page 74, lines 1-2, claim 58, page 45, line 1-5).

With reference to the instant claims 2, Trias et al. also that the growth of the cells is compared using the minimum inhibitory concentration of cells by a test compound (see page 30, lines 20-30);

With regard to claim 3-4, 16, Trias et al teach a vector (similar to pYH4 because in the instant specification pYH4 vector is described as having xyl/tet regulatory system) comprising E.coli replicons (see page 33, lines 5-10) with pxyl/tet regulatory system, multiple cloning site having NcoI, AscI restrciton enzymes (see page 48, line 4-15, page 59, line 5-16), a ribosomal

binding site, a transcriptional terminator (see page 20, line 7-18, page 24, lines 15-31, page 25, lines 1-20, page 72, lines 28-31);

With regard to claim 5, 12, 17, Trias et al. the prokaryotic organism selected from bacterial cells such as Streptococcus (S.pneumoniae), Bacillus (Bacillus subtilis), Staphyloccocus (S. aureus) (see page 11, lines 10-25).

With regard to claim 8, Trias et al. teach use of micrtiter plates to plate genes and the antimicrobial compound (see at least page 62, line 1-7, page 36, lines 3-10).

With reference to the instant claims 13-15, a method of constructing a DNA library comprising (a) identifying the open reading frame (ORFs) (see page 5, lines 26-30, page 33, lines 5-29), (b) amplifying the ORF (see page 33, lines 30-31) and (c) cloning the ORF into expression vector (see page 34, lines 1-3) the amplification of DNA was done using polymerase chain reaction (see 33, lines 30-31); a method for constructing an expression vector comprising an inducible promoter system, a ribosomal binding site, multiple cloning site allowing the cloning of intact ORF of a prokaryotic organism (see page 24, lines 15-31, page 25, lines 1-20); vector comprises replicons of E.coli (see page 33, lines 5-10). Thus the disclosure of Trias et al. meets the limitations in the instant claims

B. Claims 1, 3-7, 11-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Tally et al. (USPN. 6,436,694).

With reference to the instant claim 1, 6, Tally et al. teach a method for identifying a target of an antimicrobial compound (see column 6, lines 40-56) comprising (a) cloning the open reading frame of a gene or genes of a prokaryotic organism into an expression vector comprising inducible promoter (see column 2, lines 7-52, 7, lines 19-47, column 11, lines 63-67, column 12,

lines 47-67, column 3, lines 1-36); (b) inducing expression of the gene with an inducer in the presence of an antimicrobial compound (see column 7, lines 40-51, column 8, lines 6-13); (c) comparing growth of cells from induced gene expression in the vector to cells from uninduced gene expression in the vector (see column 8, lines 25-43, column 9, lines 23-47, column 11, lines 4-13); (d) correlating the comparison to determine if the gene is resistant to the antimicrobial compound and is target of the compound (see column 9, lines 23-47, column 18, lines 51-67, column 20, lines 9-50).

With reference to the instant claims 3-4, 16, Tally et al. also teach a vector (similar to pYH4) comprising S. aureus replicons with Em (erythromycin) selection marker, restriction enzyme sites KpnI, StuI, tet regulatory system, a ribosomal binding site (see column 12, lines 15-67, column 13, lines 1-65), and vector comprises replicons of S.aureus (see column 13, lines 1-22, column 14, lines 46-53, column 16, lines 29-48).

With regard to claim 5, 12, Tally et al. teach that the prokaryotic organism selected from bacterial cells such as Streptomyces, Bacillus anthracis, Staphyloccocus aureus (see column 5, lines 26-41).

With regard to claim 7, Tally et al. teach that the genes were fluorescence tagged to identify the expression (see column 7, lines 3-17, column 8, lines 25-43).

With regard to claim 11, Tally et al. teach that the inducer is anhydrotetracycline (see col. 4, line 24-27, col. 10, line 3-16, column 7, lines 40-46).

With reference to the instant claims 13-15, and 17, a method of constructing a DNA library comprising (a) identifying the open reading frame (ORF), (b) amplifying the ORF and (c) cloning the ORF into expression vector (see column 12, lines 14-50) the amplification of DNA

was done using polymerase chain reaction (see column 12, lines 14-50); a method for constructing an expression vector comprising an inducible promoter system, a ribosomal binding site, multiple cloning site allowing the cloning of intact ORF of a prokaryotic organism (see column 13, lines 35-50); Thus the disclosure of Tally et al. meets the limitations in the instant claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

A. Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trias et al. (WO 99/52926) and in view of Debouck et al. (Nature Genetics, supplement, Vol. 21, pp. 48-50, January 1999).

With reference to the instant claim 1, 6, Trias et al. teach a method for identifying a target of an antimicrobial compound (see page 7, lines 8-11, page 71, lines 26-31, page 72, lines 1-3,

claim 36) comprising (a) cloning the open reading frame of a gene or all genes of a prokaryotic organism into an expression vector comprising inducible promoter (see page 5, lines 26-30, page 6, lines 26-31, page 7, lines 1-3, page 22, line 1-31, page 71, lines 26-31, claim 36); (b) inducing expression of the gene with an inducer in the presence of an antimicrobial compound (see page 5, lines 3-30, page 72, lines 1-2, claim 36); (c) comparing growth of cells from induced gene expression in the vector to cells from uninduced gene expression in the vector (see page 5, lines 3-30, page 44, line 12-31, page 73, lines 5-6, claim 51); (d) correlating the comparison to determine if the gene is resistant to the antimicrobial compound and is target of the compound (see page 7, lines 25,29, Fig.4, page 5, 3-30, page 71, lines 26-31, page 72, lines 1-3, claim 36, page 73, lines 29-30, page 74, lines 1-2, claim 58, page 45, line 1-5).

However, Trias et al. did not specifically use of DNA microarray.

Debouck et al. teach a method for identification of a drug target, wherein Debouck et al. disclose that the method uses DNA microarray to identify gene expression of multiple targets in parallel to identify a drug targets (see page 48, abstract, page 49, col. 2 paragraph 3-4).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to modify a method of identifying a target of an antimicrobial compound as taught by Trias et al. with the method of identifying drug targets using DNA microarray as taught by Debouck et al. to achieve expected advantage of developing a high-throughput screening method for identifying a target of an antimicrobial compound because Debouck et al. explicitly taught the use of DNA microarrays to evaluate the effects of various treatments on gene expression in parallel to identify drug targets" (page 48, abstract, page 49, col. 2 paragraph 3-4). An ordinary practitioner would have been motivated to combine the

method of identifying a target of an antimicrobial compound as taught by Trias et al. with DNA microarray technology as taught Debouck et al. to achieve the expected advantage of developing a high-throughput method for identifying a target of an antimicrobial compound because the addition of the limitation taught by Debouck et al. would permit to screen a large number of antimicrobial compounds in parallel in a single high-throughput assay and such modification of the method is considered as obvious over the cited prior art in the absence of secondary considerations.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prabha Chunduru
SURYAPRABHA CHUNDURU
PATENT EXAMINER
3/20/06